PROMOTING IMMUNIZATION THROUGHOUT CHILDHOOD

THE NATIONAL IMMUNIZATION PROGRAM works with healthcare providers, public and private sector partners, and state and local government agencies to ensure that childhood immunizations remain at high levels. NIP also works with these partners to foster awareness of immunization recommendations and to increase knowledge about vaccines.

CHILDHOOD IMMUNIZATION SCHEDULE

ONE OF NIP'S MOST IMPORTANT ACTIVITIES is the development and distribution of the childhood immunization schedule, which summarizes recommendations for childhood vaccines in table format. Three advisory bodies collaborate to issue a single schedule of routine childhood immunizations: the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). The schedule is continually evaluated to ensure the highest level of effectiveness, efficiency, and safety in childhood immunizations. *(See the 2006 Recommended Childhood Immunization Schedule on page 11 and the 2006 Catch-up Tables on page 12.)*

VACCINES FOR CHILDREN PROGRAM

CONGRESS ESTABLISHED the Vaccines for Children Program (VFC) in 1993 to better ensure equal access to immunizations for all children. The VFC program is a state-operated federal entitlement program that removes vaccine cost as a barrier to immunization for our neediest children. More than $1.2 billion was spent by the VFC program in fiscal year 2005 to purchase vaccines for eligible children.

Over 44,100 provider sites are enrolled in the VFC program, and 32,292 of these are private provider sites. The VFC program provides public-purchased vaccine to all enrolled providers who agree to vaccinate VFC-eligible children from birth through 18 years of age. These children must be Medicaid-eligible, without health insurance, American Indian, or Alaska Native. In addition, children who have health insurance that does not cover vaccines are eligible for the VFC program if they are served through a federally qualified healthcare center or rural health clinic.

IMMUNIZATION INFORMATION SYSTEMS

STATE, COMMUNITY, AND HEALTHCARE PROVIDER IMMUNIZATION INFORMATION SYSTEMS

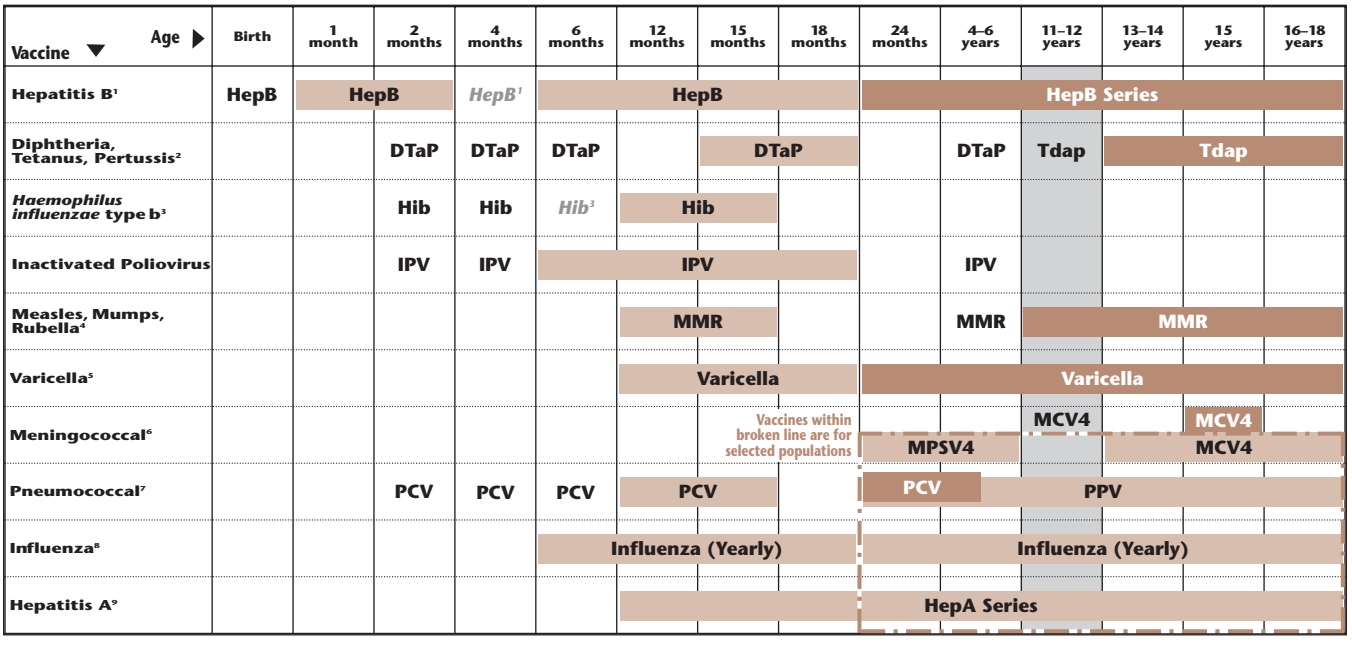
Immunization information systems (IIS) or immunization registries are confidential, computerized information systems that record, store, and provide fast access to children's immunization records. Electronic records and computer information systems are important tools to increase and sustain high vaccination coverage, especially among children. Computerized records improve healthcare providers' abilities to

update records and to share them with other healthcare providers in a practice, community, or state. Data received from 56 immunization program grantees for the 2004 Immunization Registry Annual Report (IRAR) suggest that 48% of children less than 6 years of age with two or more immunizations were participating in an IIS. This represents a 4% increase from 2003 or approximately 1 million more children who participate in an IIS.

RECENT IMMUNIZATION INFORMATION SYSTEM ACHIEVEMENTS

The Healthy People 2010 immunization information system objective is to increase to 95% the proportion of children participating in fully operational, population-based registries. Ten grantees (Alabama, Arizona, Delaware, Michigan, New Mexico, New York City, North Dakota, Oregon, Philadelphia and Wisconsin) met or exceeded the 95% participation objective as of the end of 2004. An additional seven (13%) IIS grantees (Arkansas, Mississippi, Montana, Oklahoma, Missouri, Rhode

RECOMMENDED CHILDHOOD AND ADOLESCENT IMMUNIZATION SCHEDULE* UNITED STATES • 2006



This schedule indicates the recommended ages for routine administration of currently licensed childhood vaccines, as of December 1, 2005, for children through age 18 years. Any dose not administered at the recommended age should be administered at any subsequent visit when indicated and feasible. Indicates age groups that warrant special effort to administer those vaccines not previously administered. Additional vaccines may be licensed and recommended during the year. Licensed combination vaccines may be used whenever any components of the combination are indicated and other components of the vaccine are not contraindicated and if approved by the Food and Drug Administration for that dose of the series. Providers should consult the respective ACIP statement for detailed recommendations. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a VAERS form is available at www.vaers.hhs.gov or by telephone, 800-822-7967.

Range of recommended ages **Catch-up immunization** **11–12 year old assessment**

The Childhood and Adolescent Immunization Schedule is approved by:
Advisory Committee on Immunization Practices www.cdc.gov/nip/acip • American Academy of Pediatrics www.aap.org • American Academy of Family Physicians www.aafp.org

** Please see accompanying footnotes in the Annex of this publication. The "Catch-up Schedule" follows on the next page.*

RECOMMENDED IMMUNIZATION SCHEDULE* FOR CHILDREN AND ADOLESCENTS WHO START LATE OR WHO ARE MORE THAN 1 MONTH BEHIND

UNITED STATES • 2006

The tables below give catch-up schedules and minimum intervals between doses for children who have delayed immunizations. There is no need to restart a vaccine series regardless of the time that has elapsed between doses. Use the table appropriate for the child's age.

CATCH-UP SCHEDULE FOR CHILDREN AGED 4 MONTHS THROUGH 6 YEARS

Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dose 5
Diphtheria, Tetanus, Pertussis	**6 weeks**	**4 weeks**	**4 weeks**	**6 months**	**6 months**[1]
Inactivated Poliovirus	**6 weeks**	**4 weeks**	**4 weeks**	**4 weeks**[2]	
Hepatitis B[3]	**Birth**	**4 weeks**	**8 weeks** (and 16 weeks after first dose)		
Measles, Mumps, Rubella	**12 months**	**4 weeks**[4]			
Varicella	**12 months**				
Haemophilus influenzae type b[5]	**6 weeks**	**4 weeks** if first dose given at age <12 months **8 weeks (as final dose)** if first dose given at age 12-14 months **No further doses needed** if first dose given at age ≥15 months	**4 weeks**[6] if current age <12 months **8 weeks (as final dose)**[6] if current age ≥12 months and second dose given at age <15 months **No further doses needed** if previous dose given at age ≥15 mo	**8 weeks (as final dose)** This dose only necessary for children aged 12 months–5 years who received 3 doses before age 12 months	
Pneumococcal[7]	**6 weeks**	**4 weeks** if first dose given at age <12 months and current age <24 months **8 weeks (as final dose)** if first dose given at age ≥12 months or current age 24–59 months **No further doses needed** for healthy children if first dose given at age ≥24 months	**4 weeks** if current age <12 months **8 weeks (as final dose)** if current age ≥12 months **No further doses needed** for healthy children if previous dose given at age ≥24 months	**8 weeks (as final dose)** This dose only necessary for children aged 12 months–5 years who received 3 doses before age 12 months	

CATCH-UP SCHEDULE FOR CHILDREN AGED 7 YEARS THROUGH 18 YEARS

Vaccine	Minimum Interval Between Doses		
	Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Booster Dose
Tetanus, Diphtheria[8]	**4 weeks**	**6 months**	**6 months** if first dose given at age <12 months and current age <11 years; otherwise **5 years**
Inactivated Poliovirus[9]	**4 weeks**	**4 weeks**	**IPV**[2,9]
Hepatitis B	**4 weeks**	**8 weeks** (and 16 weeks after first dose)	
Measles, Mumps, Rubella	**4 weeks**		
Varicella[10]	**4 weeks**		

** Please see accompanying footnotes in the Annex of this publication. The main Childhood and Adolescent Schedule is found on page 11.*

Island, and Tennessee) are approaching the national health objective with participation rates of 81%–94%.

Approximately 76% of public vaccination provider sites and 39% of private vaccination provider sites submitted vaccination data to an IIS during the last 6 months of 2004. Twenty-eight (50%) grantees reported that more than 95% of public provider vaccination sites submitted vaccination data to an IIS; five (9%) reported submission of vaccination data by 81%–94% of public provider vaccination sites. Seven (13%) grantees (Arkansas, Connecticut, Mississippi, New Mexico, South Dakota, Philadelphia, and San Antonio) reported that more than 95% of private provider vaccination sites submitted vaccination data to an IIS; eight (14%) (Arizona, Delaware, District of Columbia, Michigan, North Dakota, Oregon, South Carolina, and Wisconsin) reported data submission by 81%–94% of private provider sites.

In 2005, the Immunization Registry Support Branch (IRSB) in coordination with Public Health Informatics Institute (PHII) launched the **Enhanced Technical Assistance (ETA) Project**. Through the ETA, selected grantees will be provided assistance in identifying the barriers to successful IIS development and implementation, and in developing a plan of action to overcome these barriers. Currently IRSB/PHII is working with its first grantee recipient to develop a business and strategic document that describes the approach and tasks necessary to achieve the successful implementation of an IIS within the scope of their project catchment area. With this document, the grantee will implement measures to ensure their attainment of the Healthy People 2010 registry objective.

The American Immunization Registry Association (AIRA) joined the **Health Level 7 (HL7)** standards workgroup in 2005. HL7 is an international community of healthcare subject matter experts and information scientists collaborating to create standards for the electronic exchange of clinical, financial, and administrative information among healthcare oriented computer systems. AIRA members actively worked on the development of use cases for immunizations in collaboration with the HL7 pediatric Special Interest Group. AIRA continues to promote the exchange of data between managed care organizations (MCOs) and immunization registries by building the capacity of registries, while **Every Child By Two** works with individual managed care organizations and with the American Academy of Pediatrics, America's Health Insurance Plans, and the National Committee for Quality Assurance.

To assist grantees in developing a standardized approach to linking their immunization information systems with the **Vaccine Adverse Event Reporting System (VAERS)**, AIRA formed the **Vaccine Safety and Registry Community Work Group**. Collaborating with CDC, this workgroup used a consensus-based approach to analyze reporting scenarios, functional capacities, and VAERS reporting requirements. The VAERS reporting system is improving its ability to electronically receive data, including the ability to receive standard electronic messages and Web-based reports. For more information about VAERS, see the Leadership in Vaccine Safety section of this report.

CDC continues to fund **immunization information systems sentinel sites** that promote the population-based analysis of IIS data for assessment, surveillance,

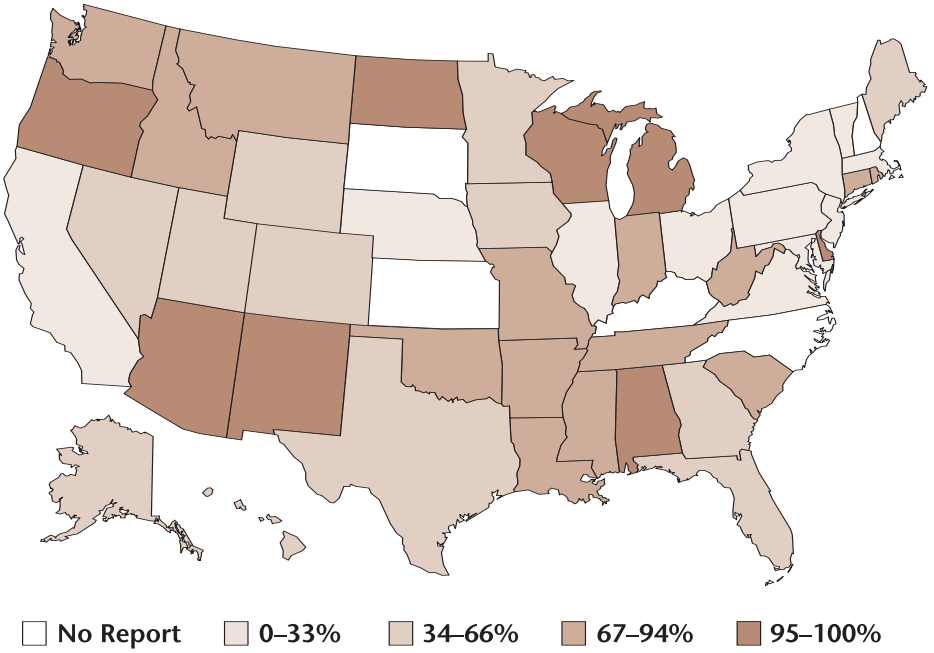
and immunization program evaluation. Funds are used by the sites in a variety of ways, including developing data quality improvement initiatives and calculating estimates of immunization coverage levels. These coverage estimates have been used at the national level to monitor the impact of vaccine shortages, most notably during the 2003–04 influenza vaccination season. To continue to expand national IIS activities, NIP invited eligible state registries to apply for funds and develop either a capacity building IIS site, aimed at improving IIS data quality and providing support for routine analysis of IIS data, or an implementation IIS site, aimed at performing numerous statistically-based, population-based assessments among children up to 18 years of age.

To assist grantees in developing standardized operational procedures in the immunization information systems, AIRA, in collaboration with CDC, used a consensus-based approach to develop guidelines on the management of the "Moved or Gone Elsewhere" and other patient immunization status in immunization information systems. It is expected that these guidelines will aid systems in the adoption of common practices for determining patient status, promote consistent use of definitions and rules of operations, thus improving data quality and usefulness of registry information.

Despite the devastation caused by Hurricane Katrina, the immunization information systems in Louisiana (LINKS), Alabama (ImmPRINT), and Mississippi (MS Immunization Registry) remained operational, and grantee IIS staff worked hard to ensure stability and accessibility for other grantees needing immunization histories for displaced children. Schools or health agencies outside of the three Hurricane Katrina-impacted states needing immunization histories for displaced children contacted their state or local immunization information system for assistance in accessing records. Virtually all grantees were given access to LINKS, where the Immunization Registry Annual Report data suggested that 79% of children aged 0–6 (289,438 of 365,874) had at least two immunizations recorded in the system. As a result, more than 20,000 immunization histories for displaced children were accessed, thereby reducing or eliminating the need for re-vaccination to be in compliance with school immunization laws.

PERCENTAGE of CHILDREN in the United States who are Between 4 Months and 6 Years of Age and have at Least Two Immunizations Registered in an Immunization Information System (IIS) as of December 31, 2004.

Source: Immunization Registry Annual Report, CY2004



Benefits of Immunization Information Systems

For **parents**, IISs provide many benefits, including

- Consolidation of immunization histories for individual children
- An accurate, official copy of a child's immunization history for personal, day care, school, or camp entry requirements
- Ensuring that a child's immunizations are up to date

- Reminders when vaccination is due
- Recall notices when vaccination has been missed
- Timely immunization for children whose families move or switch healthcare providers
- Prevention of unnecessary (redundant) immunization

For **healthcare providers**, IISs offer many advantages, including

- Consolidation of immunizations from all providers
- A reliable immunization history for any child, whether a new or continuing patient
- Definitive information on immunizations which are due or overdue
- Current recommendations and information on new vaccines
- Reminder and recall notices for patients

For **public health officials**, IISs offer

- Information to identify pockets of need, target interventions and resources, and evaluate programs
- Promotion of reminder and recall of children who need immunizations
- Assurance that providers will follow the most up-to-date recommendations for immunization practice
- Assistance with the introduction of new vaccines or changes in the vaccine schedule
- Integration of immunization services with other public health functions
- Help to monitor adverse events

Continuing Efforts for Immunization Information Systems

To reach the Healthy People 2010 objective of 95% of children participating in population-based systems and to support NIP's mission to prevent disease, disability, and death in children and adults through vaccination, the goal of immunization information systems is to generate data to support clinical decision-making by providers and to support immunization program efforts to provide strong leadership, sound decisions, effective priorities, and strong program accountability. To achieve this goal, NIP has developed plans to

- Improve grantee accountability for funding received from NIP for the development and implementation of immunization information systems
- Review procedures used to assess grantee progress and challenges in implementing IISs
- Develop an IIS Evaluation and Research agenda to promote IISs by conducting evaluation and research studies
- Develop and implement an objective evaluation or measure of IIS functionality achievement through a certification or other process
- Advance the IIS interoperability with the national initiative to develop electronic medical records and electronic health records
- Advance national strategies to use IIS data
- Support and maintain a focus for IIS at CDC

THE NATIONAL IMMUNIZATION SURVEY

THE NATIONAL IMMUNIZATION SURVEY (NIS) is the nation's primary tool for assessing immunization coverage among preschool-aged children in the United States. This random-digit-dial telephone survey is conducted annually by CDC to obtain national, state, and selected urban-area estimates of vaccination coverage rates for U.S. children aged 19–35 months. Vaccination information obtained from the telephone survey is then validated by surveys that are mailed to the children's vaccination providers.

NIS data revealed that in 2004 coverage with 4 or more doses of any diphtheria and tetanus toxoids and pertussis vaccine (DTP/DTaP/DT) was 85.5%, coverage with 3 or more doses of any poliovirus vaccine was 91.6%, coverage with 1 or more doses of measles-mumps-rubella vaccine (MMR) was 93.0%, coverage with 3 or more doses of Hib vaccine was 93.5%, and coverage with 3 or more doses of hepatitis B vaccine was 92.4%.

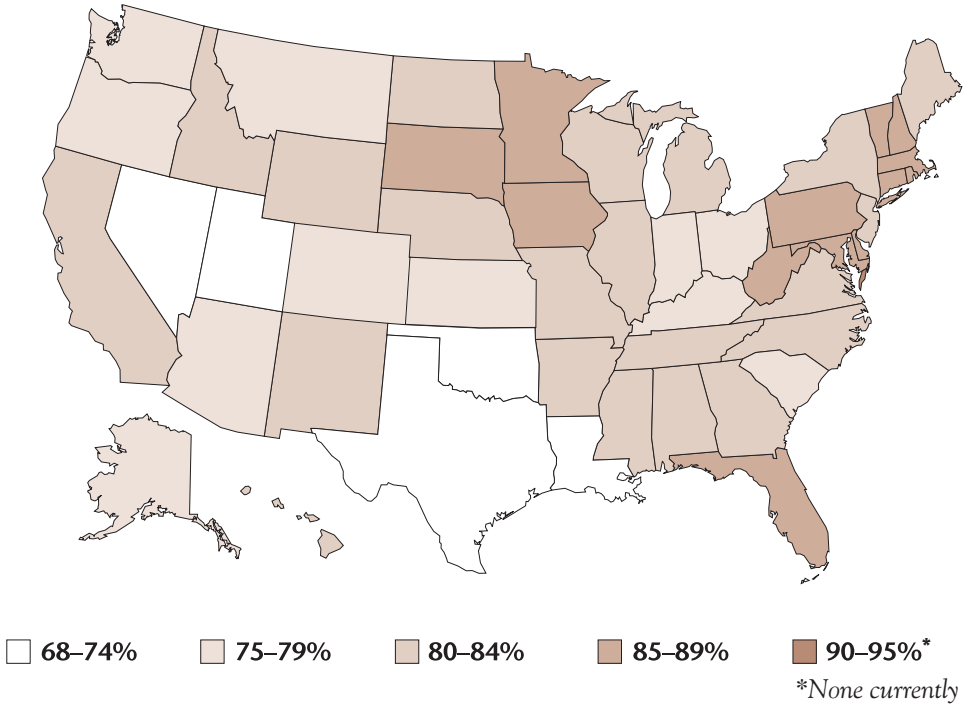
For the first time, vaccination coverage (80.9%) for the 4:3:1:3:3 series exceeded the *Healthy People 2010* goal (*objective 14-24a*) to increase to at least 80% the proportion of children aged 19-35 months who receive all vaccines recommended for universal administration for at least 5 years.

ESTIMATED VACCINATION COVERAGE of U.S. CHILDREN 19-35 Months of Age with 4:3:1:3:3

- *four or more doses of DTaP*
- *three or more doses of poliovirus vaccine*
- *one or more doses of any measles-containing vaccine*
- *three or more doses of Hib, and*
- *three or more doses of HepB*

***National Average:* 80.9% (±0.9%)**
Exceeds the Healthy People 2010 goal to increase to at least 80% the number of children receiving all vaccines recommended for universal administration.

Source: National Immunization Survey, 2004



Furthermore, coverage with one or more doses of varicella vaccine at or after the child's first birthday (unadjusted for history of varicella illness) increased from 67.8% in 2000 to 87.5% in 2004. Estimates of vaccination coverage for children aged 19–35 months based on NIS data can be found on the NIP website at *www.cdc.gov/nip/coverage*; estimates are reported there for years 1995–2004 and can be viewed by state, by certain urban reporting areas, and by demographic characteristics.

A study published in 2005 examined the variability among states in timeliness of vaccination among children aged 24 to 35 months; usually, vaccination coverage measures examine the number of vaccinations received by a certain age. The authors analyzed data from the 2000–2002 NIS and found that receipt of all vaccinations as recommended ranged among states from 2% to 26%. They concluded that children rarely receive all vaccinations as recommended. They suggest that state health departments use timeliness of vaccination along with other measures to determine children's susceptibility to vaccine-preventable diseases and to evaluate the quality of vaccination programs.*

The NIS also now collects children's entire provider-reported, influenza-vaccination histories. Beginning in 2002, ACIP encouraged annual influenza vaccination, when feasible, for all children aged 6–23 months and their household contacts, and for out-of-home caregivers for children aged less than 2 years. For the 2004-2005 influenza season, ACIP recommended vaccination for these groups.

NIS data indicate that 18% of children aged 6–23 months during the influenza season received one or more influenza vaccinations in the 2003-04 influenza season (the second year of the ACIP encouragement), and 8% of children in the age group were fully vaccinated against influenza. To be fully vaccinated, these children receive two doses if not previously vaccinated or one dose if previously vaccinated against influenza. Overall, substantial variability in influenza coverage was observed among states and selected urban reporting areas.

Rotation of the **Immunization Action Plan (IAP)** areas on the NIS was implemented in 2005 to allow for the assessment of immunization coverage in new areas with potentially low coverage. Five original IAP urban areas were not targeted for sampling by the NIS in 2005. A National Association of City and County Health Officials (NACCHO) Task Force developed recommendations for five new areas to be sampled, and five original urban IAP areas with stable, high vaccine coverage not to be targeted for sampling. Vaccine coverage estimates will be available every other year for new areas added to the NIS and for the original urban IAP areas chosen for rotation. The new areas added for 2005 included the California counties of Alameda and San Bernardino; a Denver, Colorado, tri-county area; St. Louis City and County, Missouri; and Clark County, Nevada. Original urban IAP areas chosen for rotation in 2005 included Santa Clara County and San Diego County, California; Miami-Dade County, Florida; Marion County, Indiana; and Boston, Massachusetts.

**American Journal of Public Health. 2005;95: 1367-1374)*

SCHOOL AND CHILDCARE VACCINATION SURVEYS

State laws require that children be immunized if they attend a childcare facility and when they enter school. Immunization records of children entering school are reviewed each fall. In addition, states conduct studies to validate reports from schools. Results from these studies are used to ensure high vaccination levels in the population of children enrolled in schools. Periodic assessments also are conducted in childcare facilities. A summary of the coverage results of children in schools, childcare centers, and Head Start programs and of state laws about vaccination is reported annually to the NIP. The most recent survey results can be viewed on the CDC-NIP website at *www.cdc.gov/nip/coverage/schoolsurv/overview.htm*.

IMPROVING IMMUNIZATION RATES

ASSESSMENTS OF PROGRESS

AFIX: Assessing Immunization Levels and Improving Immunization Rates at Provider Practices

Researchers at NIP led efforts to validate and promote a quality improvement strategy, **AFIX (Assessment, Feedback, Incentives, Exchange)**, that is now recommended nationwide as a standard of practice. The AFIX strategy helps public and private immunization providers determine practice coverage levels and implement programs to improve immunization rates. AFIX uses assessment and feedback about immunization levels to move the practice toward a standard of excellence. NIP research demonstrated that this strategy, which originated in a Georgia immunization program, could be successfully applied nationwide. Healthy People 2010 includes the objective that 90% of all immunization providers receive an assessment and feedback in the past two years. NIP staff are currently researching the most cost-effective methods for conducting assessment and feedback at the more than 40,000 provider sites that use federally purchased vaccine.

AFIX and VFC

AFIX has been applied through the Vaccines for Children (VFC) program to improve immunization coverage levels among preschool children. During the last decade, the VFC program has enabled low income, underinsured, uninsured, and other eligible children to receive immunizations in a "medical home" (from a consistent provider at a single site) rather than being referred to the local health department for immunization. Because many VFC participants receive immunizations from private healthcare providers, CDC initiated the VFC-AFIX project to promote AFIX to private provider sites participating in the VFC program. The year 2005 marked the fifth full year that all eligible NIP grantees participated in this initiative. NIP also offers its grantees written guidelines and technical assistance for implementing an AFIX program.

Comprehensive Clinic Assessment Software Application

The Comprehensive Clinic Assessment Software Application (**CoCASA**) is a software tool used to assess immunization coverage in healthcare settings where immunizations are delivered. CoCASA can provide diagnostic information about

immunization administration practices. The application generates diagnostic reports that identify late starts and missed opportunities for simultaneous vaccine administration, as well as children that are due or overdue for immunizations. CoCASA can assess immunization coverage for children, adolescents and adults. Because CoCASA was developed by CDC, the software is public domain and can be installed and shared with others at no cost.

IMPROVING IMMUNIZATION AMONG DISADVANTAGED CHILDREN

WOMEN, INFANTS, AND CHILDREN PROGRAM

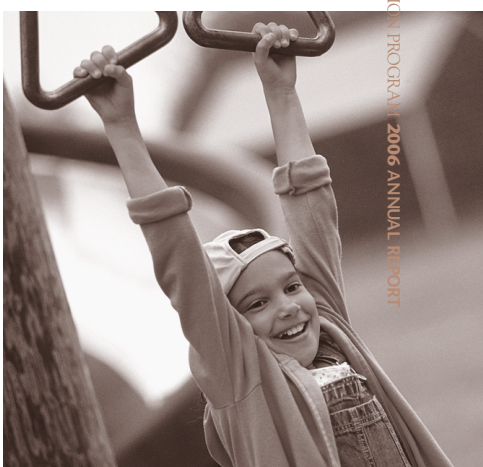
Researchers at NIP conducted a pioneer study of the effectiveness of a partnership between immunization providers and clinics that operate through the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). WIC serves 45% of infants nationwide and more than five million children under the age of five. WIC is also the single largest point of access to health services for low-income preschool children who are at the highest risk for low vaccination coverage. A White House Executive Memorandum, dated December 11, 2000, directed WIC clinics to assess the complete immunization status of their clients, a complex task given the nearly two dozen required doses of recommended vaccines. Because many clinics did not have the resources to carry out a complete assessment, NIP researchers developed and validated a simpler alternative, assessing coverage for a single vaccine —DTaP—as a proxy for assessing the complete vaccination record. This assessment method went into effect in late 2002 and has resulted in an increase in the number of WIC clinics nationwide that offer immunization assessment and referral as part of standard operating procedures.

REDUCING DISPARITIES AMONG RACIAL AND ETHNIC POPULATIONS

Eliminating health disparities among racial and ethnic populations in the United States is a major public health goal. However, in recent years, disparities in immunization rates between black and white children have been increasing, especially in certain areas. Therefore, NIP is supporting projects that may lead to reductions in these disparities. Beginning in late 2005, NIP began funding two projects aimed at reducing racial and ethnic disparities in childhood immunization. The purpose of these community-based demonstration projects is to identify, implement and evaluate interventions that will result in a statistically significant reduction in racial disparities in immunization coverage levels between black children 19–35 months of age and children of other races. These interventions include both enhancement of healthcare utilization and strategies to reduce missed opportunities for immunization.

IMPROVING VACCINE MANAGEMENT AND DELIVERY

NIP distributes over 60 million doses of pediatric vaccine every year, almost 60% of the pediatric vaccine used in the United States. The bulk of this vaccine is distributed



through the Vaccines for Children program. VFC has been a recognized success, consistently increasing provider enrollment, improving access for eligible children, and improving national immunization levels. However, many vaccine management and accountability processes are still conducted in ways established more than a decade ago.

VACCINE MANAGEMENT BUSINESS IMPROVEMENT PROJECT

In late 2003, NIP was challenged by HHS and by the President's Management Agenda to improve its business practices. New requirements, such as implementing a national pediatric stockpile and eliminating non-compliant funding practices, compelled NIP to re-examine the operating model for vaccine programs. Due to the complexity of the existing vaccine supply system, HHS, CDC, and the Government Accountability Office (GAO) also requested an analysis of the current system. Most methods and processes used to manage vaccines are derived from models put into place with the inception of the VFC program 10 years ago, and some processes were first used as early as the 1960s. These processes include stand-alone computer applications, offline spreadsheets, and paper-based, manually updated records. No uniform process to manage and track supplies is available, and no electronic or automated system supports or oversees the distribution, supply, and availability of vaccines. Yet over the past decade, the number of children served and the number of doses of vaccine provided have increased dramatically. In addition, several vaccines have been added to the list of recommended childhood vaccines. The processes that were adequate to manage and serve participants in 1994 are not sufficient for the public health needs of the twenty-first century. As a result of these requirements and concerns, the **Vaccine Management Business Improvement Project (VMBIP)** was initiated.

VMBIP is intended to simplify processes for ordering, distributing, and managing vaccines. The program will improve responses to public health crises related to disease outbreaks, vaccine shortages, and disruption of the vaccine supply. A more efficient vaccine supply system will, in turn, result in the redirection of public health resources from vaccine distribution to other critical public health activities which have improved immunization coverage. The project will also improve the accountability of the VFC program. Finally, the project will significantly reduce the lead time between orders for and delivery of vaccine and will enable the direct delivery of vaccines to providers.

NIP gathered a team to analyze the systems for managing and distributing vaccines and recommend improvements to them. This team spent the early part of 2004 examining the entire vaccine supply chain, from manufacturers to providers. In addition to working with CDC headquarters staff in Atlanta, the team visited ten state and local immunization projects, four vaccine manufacturers, and two vaccine distributors. The team studied many aspects of the VFC program, including funds management, vaccine distribution, provider ordering, inventory management, and the operation of the national pediatric stockpile.

In April 2004, the VMBIP team presented its findings to CDC and NIP leadership. A much more consolidated approach to vaccine ordering and distribution was

recommended. This new model departs from the current fragmented, decentralized approach and shows, at any time, where the product is in the supply chain—information essential to improving the nation's vaccine supply. The VMBIP team developed a detailed description of the components of a robust vaccine management program. The team has engaged over 70 staff members from federal and state immunization programs and set up workgroups for all major aspects of the program, including Ordering and Distribution, Vaccine Stockpile, Systems, Fiscal Operations, Vaccine Management and Accountability, and Communications. The workgroups have identified requirements for the new program model and drafted a request for proposals for distribution services.

Throughout this period of investigation, the team collaborated with many groups involved in vaccine programs, including leadership within NIP, CDC, HHS, and the National Vaccine Program Office (NVPO), partner organizations such as the Association of Immunization Managers (AIM), the Association of State and Territorial Health Officials (ASTHO), Every Child by Two, the National Association of County and City Health Officials (NACCHO), the American Immunization Registry Association (AIRA), and immunization program managers. The team has been encouraged by the positive feedback and the constructive suggestions received thus far and will continue to work closely with all vaccine program stakeholders.

The VMBIP team recently accomplished a key milestone with transition to a different methodology for obligating vaccine funding. Vaccine funds are now obligated against manufacturer contracts, enabling CDC to better match vaccine funds with grantee needs. In addition, a request for proposal for centralized distribution was released and a contract award is anticipated in the spring of 2006. Planning continues for the piloting of the centralized distribution process, scheduled to begin in mid-2006, involving several grantee states and urban cities. When the pilot programs have been validated, the new system will be rolled out nationwide, beginning with those that already use commercial distributors, then moving to those states that now distribute vaccine through state-sponsored systems. By late 2008, it is anticipated all 64 grantees will have transitioned to the new centralized distribution model.

NEW VACCINE SURVEILLANCE NETWORK

The New Vaccine Surveillance Network (NVSN), established in 1999, assesses the impact of new vaccines and new vaccine policies on children who are hospitalized or seen in emergency departments or outpatient settings in Rochester, New York; Nashville, Tennessee; and Cincinnati, Ohio. Highlights of work conducted during 2005 include a study focused on

- Estimating the effectiveness of influenza vaccine in preventing laboratory-confirmed influenza hospitalizations among children under 5 years of age
- Assessment of the benefit of maternal influenza vaccination in protecting infants less than 6 months of age who are too young to receive influenza vaccine
- Surveillance for pertussis disease among children less than 6 months of age
- Assessment of the impact of pneumococcal conjugate vaccine on otitis media, and pneumonia

Oftentimes, information gained from these studies is used to in the development of new vaccine recommendations for the United States. For example, through data collected and analyzed by the NVSN, NIP learned that a high rate of hospitalizations, emergency room visits, and doctors' office visits were associated with influenza in young children. NIP also learned that influenza vaccine helped prevent laboratory-diagnosed influenza during the 2003-2004 influenza season. This information was important in establishing the recent ACIP recommendation to vaccinate children 6 to 23 months of age routinely.

In response to the February 2006 licensure of the new rotavirus vaccine (RotaTeq®), the NVSN will conduct rotavirus surveillance in the upcoming season to estimate baseline disease burden among children under 3 years of age in hospital, emergency department and outpatient practice settings in the sites' counties. Surveillance data will provide important information for monitoring post licensure rotavirus vaccine performance and impact of the vaccine program on rotavirus disease.

Vaccine University

In 2005, NIP convened its first Vaccine University November 30 in Atlanta, Georgia. Three hundred and twenty-five participants registered for the two-and-a-half-day training, representing over 90% of the immunization programs.

This vaccine training program was developed specifically for Immunization Program grantee staff members who provide daily oversight to the Vaccines for Children (VFC), Vaccine Management, and AFIX immunization programs at the state or local level. Vaccine University was planned by a workgroup within the Immunization Services Division (ISD) at NIP and one member of the Association of Immunization Program Managers (AIM). Educational tracks were offered for each of the VFC, Vaccine Management, and AFIX programs.

Presentation highlights from the Vaccine University training included:

- Forecasting vaccine need for 2006 and beyond
- The Top Ten Vaccine Storage and Handling Issues
- Training on the new Comprehensive CASA software in context of the overall AFIX process
- Understanding CDC vaccine contract procurement, management and distribution activities
- Getting the most out of VFC site visits

Of the participants who completed the training evaluation, 98% reported that they "would like to see Vaccine University held again," and 58% thought it should be held on an annual basis. Discussions are underway about future Vaccine University training.

AFIX & VFC

SPECIAL

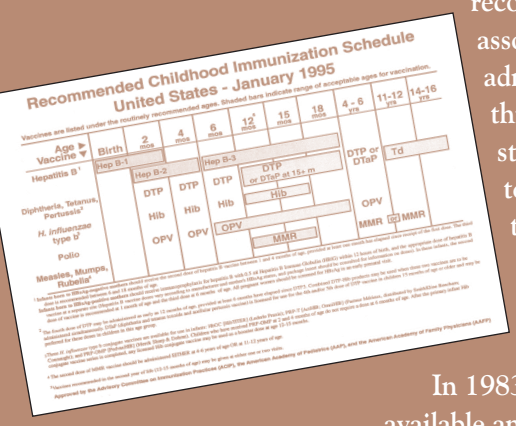
REPORT

VACCINES: PUBLIC HEALTH ECONOMICS

Vaccines have had a profound impact on the health of people around the world from the eradication of smallpox worldwide to the elimination of polio and rubella in the western hemisphere. As one of the most cost-effective interventions in the history of public health, vaccines have been and continue to be responsible for a dramatic reduction in the incidence of numerous life-threatening diseases. Figures 1 and 2 illustrate the percent reduction in estimated annual cases of vaccine-preventable diseases in the United States from twentieth century pre-vaccine era to the number of cases reported in 2004.

An integral part of achieving this success has been the significant investment of philanthropic and public health organizations, pharmaceutical companies, as well as local and state governments in vaccine development, production and administration. This investment in immunization has led to the highest vaccination coverage rates and lowest rates of vaccine-preventable diseases since the first vaccines were administered.

A vaccine goes through years of research and clinical trials before making it to the public and private market. Even after vaccines have been recommended federally, high costs are associated with their distribution and administration, from cost incurred through federal contracts through the state level where they are distributed to the provider level for administration. Figure 4 outlines the basic steps involved from vaccine research and development to monitoring coverage and distribution.



In 1983, vaccines for seven diseases were available and recommended for routine use in the United States—measles, mumps, rubella, diphtheria, tetanus, pertussis, and polio. In 2005, vaccines for 14 diseases were available and recommended for use. It is projected that more than 20 vaccines may be available for use in preventing disease by the year 2020. Figure 3 illustrates the increasing numbers of recommended vaccines available and projected within the next 15 years. Accompanying the benefits of these new vaccines will be logistic and economic challenges.

Working with epidemiologists, program consultants, state and local program managers, and academic researchers, NIP economists are addressing a broad range of research topics, including evaluation of the cost-effectiveness and cost-benefit of vaccines and vaccination programs, analysis of vaccine markets and policies, including factors affecting U.S. manufacturers' decisions to produce vaccines, and estimations of illness costs of vaccine-preventable diseases. Research results from NIP's economics team have seen worldwide distribution and use.

An economic evaluation of the seven-vaccine routine immunization series found that it results in billions of dollars of direct cost savings and even greater savings when examined from a societal perspective. A study of varicella vaccine showed cost savings for that vaccine as well and required a novel approach to analysis. NIP economic team staff examined administrative and billing data and determined the impact of the varicella vaccination program on medical visits and associated expenditures. Economists from NIP collaborated with economists and epidemiologists from NCID to provide economic data used by the ACIP in recommending meningococcal conjugate vaccine for adolescents. An analysis of vaccine markets has provided better understanding of how vaccine manufacturers make production decisions and insights into how they price vaccines. These and other activities demonstrate how NIP is leading the way in the development of public health economics research.

Figure 1.

COMPARISON OF 20TH CENTURY ESTIMATED ANNUAL CASES AND 2004 REPORTED CASES OF VACCINE-PREVENTABLE DISEASES (PRE-1990 VACCINES)

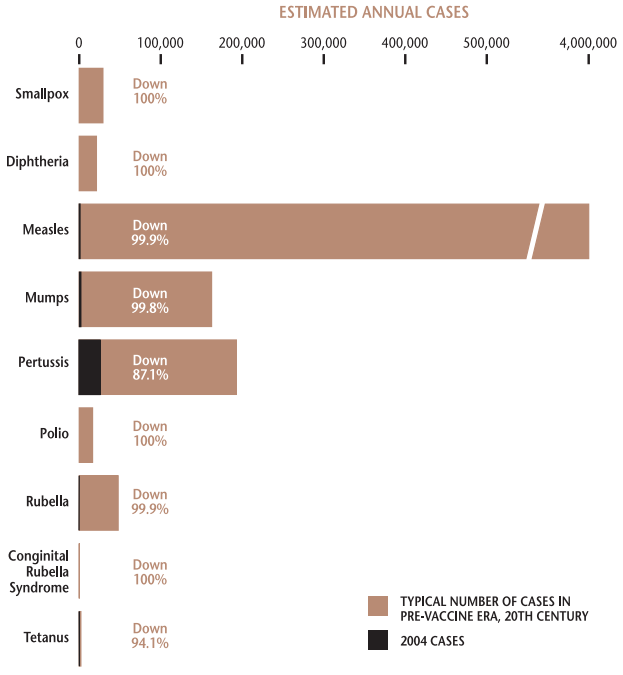


Figure 2.

COMPARISON OF PRE-VACCINE ERA ESTIMATED ANNUAL CASES AND 2004 ESTIMATED CASES OF VACCINE-PREVENTABLE DISEASES (POST-1990 VACCINES)

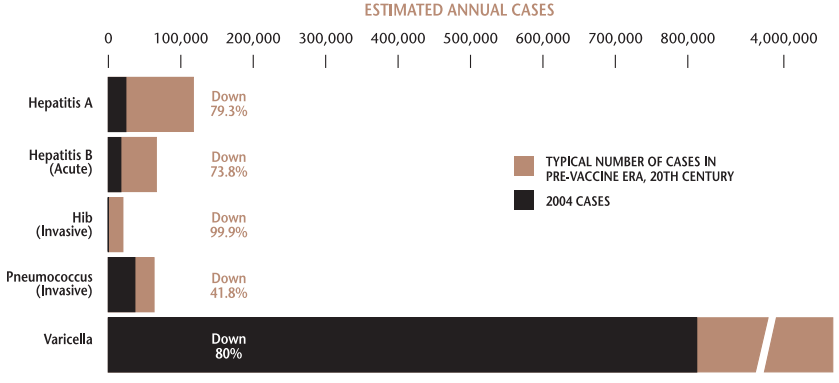


Figure 3.

VACCINE-PREVENTABLE DISEASES — YESTERDAY, TODAY, TOMORROW

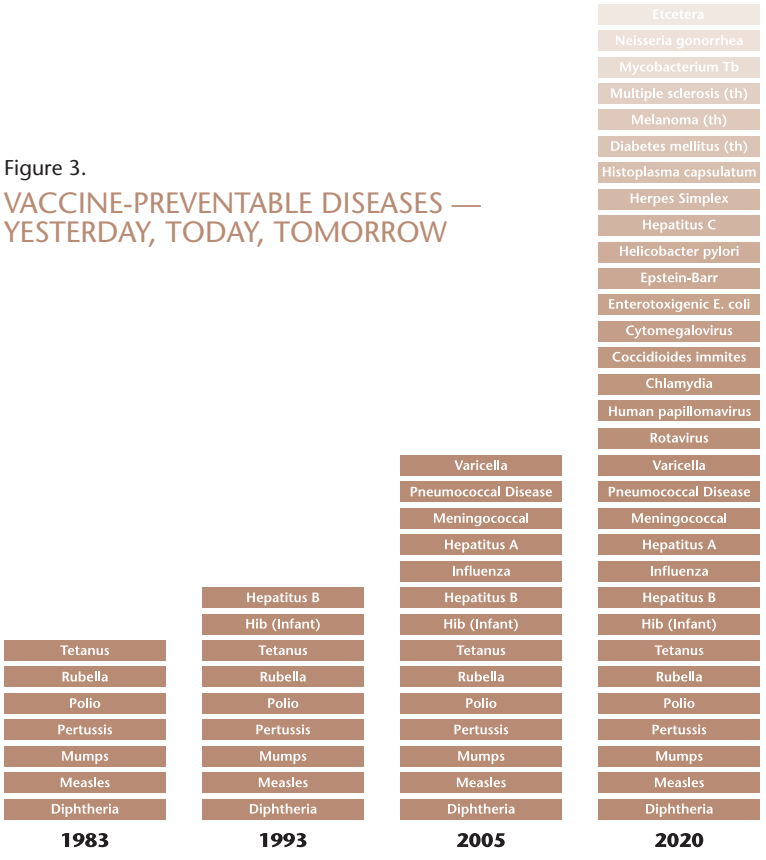


Figure 4.

VACCINE — FROM RESEARCH TO MARKET